

1. (Amended) A valve assembly for use in a medical product having a fluid path, the valve assembly configured to selectively pass fluids in one direction along the fluid path and to prevent backflow in the opposite direction along the fluid path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

the valve member formed at least in part by a material having a durometer of less than about 12 Shore.

2. The valve assembly as in claim 1, wherein the opposing walls of the valve member each have a generally uniform thickness of about 0.040 inches.

3. (Amended) The valve assembly as in claim 1, wherein the valve member material has a durometer of about 8 to less than about 12 Shore.

4. The valve assembly as in claim 1, wherein the valve member material has a durometer of about 10 Shore.

5. The valve assembly as in claim 1, wherein the valve member peripheral portion and walls form a duckbill valve.

6. (Amended) A medical product defining a fluid path, the medical product comprising a valve

assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

the valve member formed at least in part by a material having a durometer of less than about 12 Shore.

7. The medical product as in claim 6, wherein the medical product is a gastrostomy catheter, the fluid path defined between a patient's body cavity and an exterior of the body.

8. - 22. (Cancel)

23. A valve assembly for use in a medical product having a fluid path, the valve assembly configured to selectively pass fluids in one direction along the fluid path and to prevent backflow in the opposite direction along the fluid path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

at least one of the flexible opposing walls defining a first portion including a material having a durometer of about 50 Shore and a second portion having a durometer of less than about 20 Shore, the second portion being disposed at the respective end of the at least one wall, and the first portion being disposed spaced from the respective end.

24. The valve assembly as in claim 23, wherein the at least one wall has a thickness of about 0.040 inches.

25. The valve assembly as in claim 23, wherein the second portion of the at least one wall includes a material having a durometer of about 10 Shore.

26. A medical product defining a fluid path, the medical product comprising a valve assembly disposed in the path, the valve assembly comprising:

a valve housing defining an opening having a central axis, the opening extending through the valve housing such that the opening forms part of the fluid path through the medical product;

a valve member disposed within the opening, the valve member having a single seal interface defined by at least two opposing flexible walls biased towards each other to a sealing position, the valve member having a peripheral portion with the opposing flexible walls extending from the peripheral portion toward the central axis, the opposing flexible walls including ends that contact each other along the single seal interface; and

at least one of the flexible opposing walls defining a first portion including a material having a durometer of about 50 Shore and a second portion having a durometer of less than about 20 Shore, the second portion being disposed at the respective end of the at least one wall, and the first portion being disposed spaced from the respective end.

27. The medical product as in claim 26, wherein the medical product is a gastrostomy catheter, the fluid path defined between a patient's body cavity and an exterior of the body.

28. (New) The medical product as in claim 6, wherein the valve member has a durometer of about 8 to less than about 12 Shore.

#### **REMARKS**

In the Office action of December 5, 2002, claims 1, 3-7, 21, 23, and 25-27 were rejected under 35 U.S.C. §103(a) as being unpatentable over Willis et al. (U.S. Patent No. 5,997,503) in view of Mikhail et al. (U.S. Patent No. 6,050,934).

Also, claims 2, 20, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Willis in view of Osbourne et al. (U.S. Patent Publication No. 0049501) or Copenhaver et al. (U.S. Patent No. 5,720,734).